Supreme Court, U.S.
FILED
AUG 3 0 2006
OFFICE OF THE CLERK

No. 05-608

IN THE

Supreme Court of the United States

MEDIMMUNE, INC.,
Petitioner,

v.

GENENTECH, INC., *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF FOR PETITIONER

HARVEY KURZWEIL
ALDO A. BADINI
HENRY J. RICARDO

DEWEY BALLANTINE LLP
1301 Avenue of the Americas
New York, New York 10019
(212) 259-8000

WILLIAM C. BERTRAND, JR.
JONATHAN KLEIN-EVANS

MEDIMMUNE, INC.
1 MedImmune Way
Gaithersburg, Maryland 20878
(301) 398-4625

JOHN G. KESTER *
PAUL B. GAFFNEY
JANET C. FISHER
AARON P. MAURER
MICHAEL T. MORLEY

WILLIAMS & CONNOLLY LLP
725 12th Street, N.W.
Washington, D.C. 20005
(202) 434-5000

ELLIOT M. OLSTEIN

CARELLA BYRNE BAIN
GILFILLAN CECCHI
STEWART & OLSTEIN
Five Becker Farm Road
Roseland, New Jersey 07068
(973) 994-1700

* Counsel of Record

Attorneys for Petitioner

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
ARGUMENT IN REPLY	1
1. The Governing Decisions	1
2. "Reasonable Apprehension of Suit."	4
3. Justiciability	5
A. Standing	5
B. Ripeness	8
4. The License	10
5. "Settled Expectations."	12
6. *Lear* and Licensee Estoppel	13
7. Discretion	15
8. Practical Consequences	18
CONCLUSION	20

TABLE OF AUTHORITIES

Page

Cases:

Abbott Labs. v. *Gardner*, 387 U.S. 136 (1967) 9
Aetna Life Ins. Co. v. *Haworth*, 84 F.2d 695 (8th Cir. 1936), *rev'd*, 300 U.S. 227 (1937) 2
Aetna Life Ins. Co. v. *Haworth*, 300 U.S. 227 (1937) 2, 3, 4, 6, 7
Allen v. *Wright*, 468 U.S. 737 (1984) 8
Altvater v. *Freeman*, 319 U.S. 359 (1943) 3, 5, 7, 9, 16
Automatic Radio Mfg. Co. v. *Hazeltine*, 339 U.S. 827 (1950) 5
Avia Group Int'l, Inc. v. *L.A. Gear Cal., Inc.*, 853 F.2d 1557 (Fed. Cir. 1988) 9
Bennett v. *Spear*, 520 U.S. 154 (1997) 5
Blonder-Tongue Labs. v. *University of Ill. Foundation*, 402 U.S. 313 (1971) 18, 19, 20
Borey v. *National Union Fire Ins. Co.*, 934 F.2d 30 (2d Cir. 1991) 10
Brillhart v. *Excess Ins. Co.*, 316 U.S. 491 (1942) 15
Brulotte v. *Thys Co.*, 379 U.S. 29 (1964) 19
Business Forms Finishing Serv., Inc. v. *Carson*, 452 F.2d 70 (7th Cir. 1971) 11
C.R. Bard, Inc. v. *Schwartz*, 716 F.2d 874 (Fed. Cir. 1983) 12, 13
Cardinal Chem. Co. v. *Morton Int'l, Inc.*, 508 U.S. 83 (1993) 4, 7, 12, 16, 20
DaimlerChrysler Corp. v. *Cuno*, 126 S. Ct. 1854 (2006) 1, 6
eBay Inc. v. *MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006) 16, 18
Elk Grove Unified School Dist. v. *Newdow*, 542 U.S. 1 (2004) 8
Flex-Foot, Inc. v. *CRP, Inc.*, 238 F.3d 1362 (Fed. Cir. 2001) 11

TABLE OF AUTHORITIES—Continued

Page

Gen-Probe Inc. v. *Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir.), *pet'n for cert. dismissed*, 543 U.S. 941 (2004) 1, 12, 13, 15, 19

Jervis B. Webb Co. v. *Southern Sys., Inc.*, 742 F.2d 1388 (Fed. Cir. 1984) 9

Kewanee Oil Co. v. *Bicron Corp.*, 416 U.S. 470 (1974) 15

Kinsman v. *Parkhurst*, 18 How. 289 (1856) 13

Kraly v. *National Distillers & Chem. Corp.*, 502 F.2d 1366 (7th Cir. 1974) 11

Laboratory Corp. v. *Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) 20

Lake Carriers' Ass'n v. *MacMullan*, 406 U.S. 498 (1972) 9

Lear, Inc. v. *Adkins*, 395 U.S. 653 (1969) 1, 5, 11, 13, 14, 19, 20

Lochner v. *New York*, 198 U.S. 45 (1905) 20

Lujan v. *Defenders of Wildlife*, 504 U.S. 555 (1992) 6

Marshall v. *Marshall*, 126 S. Ct. 1735 (2006) 7

Martin v. *Franklin Capital Corp.*, 126 S. Ct. 704 (2005) 15

Maryland Cas. Co. v. *Pacific Coal & Oil Co.*, 312 U.S. 270 (1941) 2, 3, 4, 7, 10, 16

Maryland Cas. Co. v. *United Corp.*, 111 F.2d 443 (1st Cir. 1940) 16

Matsushita Elec. Indus. Co. v. *Epstein*, 516 U.S. 367 (1996) 15

MedImmune, Inc. v. *Centocor, Inc.*, No. 05-656 ... 13, 17

Murray v. *Charleston*, 96 U.S. 432 (1877) 20

Nashville, C. & St. L. Ry. v. *Wallace*, 288 U.S. 249 (1933) 5

National Park Hospitality Ass'n v. *Department of Interior*, 538 U.S. 803 (2003) 9

TABLE OF AUTHORITIES—Continued

	Page
118 East 60th Owners, Inc. v. *Bonner Properties, Inc.*, 677 F.2d 200 (2d Cir. 1982)	12
Ponte v. *Real*, 471 U.S. 491 (1985)	15
Pope Mfg. Co. v. *Gormully*, 144 U.S. 224 (1892)	11
Principal Life Ins. Co. v. *Robinson*, 394 F.3d 665 (9th Cir. 2005)	10
Public Serv. Comm'n v. *Wycoff Co.*, 344 U.S. 237 (1952)	9
Steel Co. v. *Citizens for a Better Environment*, 523 U.S. 83 (1998)	11
Steffel v. *Thompson*, 415 U.S. 452 (1974)	8, 16
Studiengesellschaft Kohle, m.b.H. v. *Shell Oil Co.*, 112 F.3d 1561 (Fed. Cir.), *cert. denied*, 522 U.S. 996 (1997)	13
Texas v. *United States*, 523 U.S. 296 (1998)	10
United States v. *Harvey Steel Co.*, 196 U.S. 310 (1905)	14
United States v. *SCRAP*, 412 U.S. 669 (1973)	6
Valley Forge Christian College v. *Americans United for Separation of Church & State, Inc.*, 454 U.S. 464 (1982)	6
Vermont Agency v. *United States ex rel. Stevens*, 529 U.S. 765 (2000)	6
Waterman v. *Mackenzie*, 138 U.S. 252 (1891)	19
Willing v. *Chicago Auditorium Ass'n*, 277 U.S. 274 (1928)	5
Wilton v. *Seven Falls Co.*, 515 U.S. 277 (1995)	16
Yee v. *City of Escondido*, 503 U.S. 519 (1992)	15
Zenie Bros. v. *Miskend*, 10 F. Supp. 779 (S.D.N.Y. 1935)	9

Constitutional Provisions:

U.S. Constitution, Article III	1, *passim*
Fourteenth Amendment	20

TABLE OF AUTHORITIES—Continued

Page

Statutes:

Declaratory Judgment Act, 28 U.S.C. § 2201 ....1, *passim*
17 U.S.C. § 506 20
28 U.S.C. § 1338 7
35 U.S.C. § 271 9
35 U.S.C. § 284 ..... 9, 20

Rules:

Federal Rules of Civil Procedure, Rule 57 ..... 8, 14

Miscellaneous:

BLACK'S LAW DICTIONARY (8th ed. 2004)..... 11
Borchard, *Justiciability*, 4 U. CHI. L. REV. 1 (1936)..... 5
Brief of Defendant-Appellee City of Hope, *MedImmune, Inc.* v. *Genentech, Inc.*, Nos. 04-1300, 04-1384, U.S. Ct. Apps., Fed. Cir. (Sept. 14, 2004)..... 4
Brief for the United States as *Amicus Curiae*, *Lear, Inc.* v. *Adkins*, NO. 56, OT 1968 (Oct. 25, 1968)..... 18
B. BRUNSVOLD & D. O'REILLEY, DRAFTING PATENT LICENSE AGREEMENTS (5th ed. 2004).. 13
City of Hope's Answer Brief on the Merits, *City of Hope Nat'l Med. Ctr.* v. *Genentech, Inc.*, No. S129463, S. Ct. Cal. (Sept. 19, 2005)..... 17
Corrected Brief of Defendant-Appellee Genentech, Inc., *MedImmune, Inc.* v. *Genentech, Inc.*, Nos. 04-1300, 04-1384, U.S. Ct. Apps., Fed. Cir. (Sept. 24, 2004) 4
FEDERAL TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003)..... 18

TABLE OF AUTHORITIES—Continued

	Page
Fisher, *The Licensee's Choice: Mechanics of Successfully Challenging a Patent Under License*, 6 TEXAS INTELL. PROP. L.J. 1 (1997) ..	13
C. FRIED, CONTRACT AS PROMISE: A THEORY OF CONTRACTUAL OBLIGATION (1981)	20
Friedmann, *Social Insurance and the Principles of Tort Liability*, 63 HARV. L. REV. 241 (1949)	7
Friendly, *Mr. Justice Harlan, as Seen by a Friend and Judge of an Inferior Court*, 85 HARV. L. REV. 382 (1971)	14
Holmes, *The Path of the Law*, 10 HARV. L. REV. 457 (1897)	20
McCarthy, *"Unmuzzling" the Patent Licensee: Chaos in the Wake of Lear v. Adkins*, 59 J. PAT. OFF. SOC'Y 544 (1977)	13
J. MOORE, *et al.*, MOORE'S FEDERAL PRACTICE (3d ed. 2006)	5, 7, 13
Raack, *A History of Injunctions in England Before 1700*, 61 IND. L.J. 539 (1986)	10
RESTATEMENT (2D), TORTS (1965)	7
Sharp, *Pacta Sunt Servanda*, 41 COLUM. L. REV. 783 (1941)	20
P. STEIN, REGULAE IURIS (1966)	6
Warren, *Volenti Non Fit Injuria in Actions of Negligence*, 8 HARV. L. REV. 457 (1895)	7

REPLY BRIEF FOR PETITIONER

At issue is whether petitioner as a patent licensee is barred from the federal courts for continuing to pay royalties while disputing the validity, enforceability and infringement of the patent. The Federal Circuit insists that to resolve the dispute in federal court, a licensee first must raise the stakes by ceasing payment and inviting charges of breach of contract and patent infringement. That is hardly a practical solution to a recurrent kind of business disagreement; it is not demanded by Article III; and it is exactly the sort of wasteful behavior, costly to all parties, that the Declaratory Judgment Act was enacted to make unnecessary.

The Declaratory Judgment Act authorizes relief to "declare the rights and other legal relations" of "any interested party" in a "case of actual controversy" within the jurisdiction of the federal courts. 28 U.S.C. § 2201(a). Under decisions of this Court followed for seven decades, the provisions of that statute, and the Article III requirements it incorporates, are satisfied. The Federal Circuit decision under review, and the one two years ago that gave rise to it,[1] were a mistaken deviation.

What respondents seek "would amount to a significant revision of our precedent interpreting Article III." *Daimler-Chrysler Corp.* v. *Cuno*, 126 S. Ct. 1854, 1867 (2006). Nor would such a revision well serve the patent laws. "Licensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor's discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification." *Lear, Inc.* v. *Adkins*, 395 U.S. 653, 670 (1969).

1. The Governing Decisions.

Federal declaratory-judgment law began with three significant decisions by this Court during the decade after the Act was passed. This case fits comfortably within those deci-

---

[1] *Gen-Probe Inc.* v. *Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir.), *pet'n for cert. dismissed*, 543 U.S. 941 (2004).

sions, which have stood unchallenged and respected for three generations. Respondents' arguments strikingly resemble those made unsuccessfully in the 1930s and 1940s.[2]

1. Respondents seek to discount this Court's foundational decision in *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227 (1937), setting it aside as simply a "mirror image" "symmetrical" suit, Gen. 21; COH 15. Respondents ignore not only *Aetna's* principle but its facts. None of the five insurance policies in *Aetna* required payment to the beneficiary spouse until the death of the insured husband. 300 U.S. at 237. Three called for no other payments; two provided for small payments to the husband in the event of permanent disability, but it was argued without contradiction that those amounts were too small to satisfy the federal jurisdictional amount, see 300 U.S. at 234 (argument for respondents), an issue this Court found unnecessary to reach. 300 U.S. at 243. This Court sustained jurisdiction as to all policies and both defendants.

2. *Maryland Cas. Co.* v. *Pacific Coal & Oil Co.*, 312 U.S. 270 (1941), contains perhaps the most succinct (and often quoted) statement of what declaratory actions require: "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality." *Id.* at 273. Each of those requirements is met here, and respondents never

---

[2] *E.g.*, Gen. 1, 16, 27 ("judicial advice"), 14, 15, 16, 17 ("hypothetical"), 25 ("injury . . . will likely never occur"); COH 11 ("obtaining advice") ("contingency that may never occur"), 22, 29, 30 ("no ripe controversy"), 19, 20, 21 ("hypothetical"), 31 ("entirely contingent and remote") ("MedImmune has the unilateral power to decide"). *Compare* the opinion this Court reversed in *Aetna*: "advisory opinions;" "no suit is threatened and no demand made by the defendants;" "[t]he right of cancellation is one which the plaintiff may exercise itself without asking the aid of the court;" "too remote and vague;" "do not show that any right of the plaintiff is presently being invaded or imminently and prejudicially affected." *Aetna Life Ins. Co.* v. *Haworth*, 84 F.2d 695, 697-98 (8th Cir. 1936), *rev'd*, 300 U.S. 227 (1937). "Gen." and "COH" refer to respondents' respective briefs, "C.A.A." to the joint appendix in the Court of Appeals.

directly respond to them. Genentech scarcely mentions *Maryland Casualty*, grouping it as a "mirror image" case, but acknowledging that the collision victim defendant in that case had not sued the insurer (and, having brought an action against only the insured in state court, could not have done so without first winning a judgment). Gen. 21 & n.13; see also COH 16. The rule of *Maryland Casualty*, which has stood the test of decades, is the established rule. The present dispute certainly has no less "immediacy and reality" than the potential claim held sufficient in *Maryland Casualty*.

3. *Altvater* v. *Freeman*, 319 U.S. 359 (1943), is inescapable for its specific holding in the patent-license context that a party making royalty payments is not thereby placed outside the Declaratory Judgment Act:

> "It is said that so long as petitioners are paying royalties . . . there is only an academic, not a real controversy, between the parties. . . . *The fact that royalties were being paid did not make this a 'difference or dispute of a hypothetical or abstract character.'*"

319 U.S. at 364, quoting *Aetna*, 300 U.S. at 240 (emphasis supplied). Respondents would disregard *Altvater* because the license royalty payments there had been reinforced by an injunction. Gen. 26-27; COH 24-25.[3] But this Court emphasized that the royalty payments (there as here "under protest") were made not only in accordance with the injunction, but also because not to pay would "risk not only actual but treble damages in infringement suits." *Id.* at 365. *Altvater* recognized that risk of treble damages, as well as of other sanctions, independently satisfied Article III and the Declaratory Judgment Act.

---

[3] Although the lower courts had ruled the license itself no longer applicable, the injunction implementing it remained in effect and, along with the risk of infringement penalties, "preserve[d] the right . . . to challenge the legality of the claim," as the licensees continued to pay royalties in the amounts required by the license. 319 U.S. at 362, 365.

2. "Reasonable Apprehension of Suit."

The Federal Circuit held that Article III requires more than a concrete and immediate dispute as to legal rights—the standard of *Maryland Casualty*—but also a "reasonable apprehension of suit"—which, it went on to hold, as a matter of law cannot exist if a licensee is in good standing paying royalties. P.C.A. 4a-6a.

Respondents strenuously argued for that rule in the Court of Appeals, Gen. C.A. Br. 21, COH C.A. Br. 7-8, and they defended it, as their lead argument, in their opposition to certiorari. Br. Opp. 8-10, 16 ("the point itself is unassailable"). City of Hope now disowns the rule, saying that it "confused matters" and "is not at issue here," because the Federal Circuit additionally requires that a declaratory plaintiff be "actually or imminently engaging in allegedly infringing conduct," and that "is not satisfied here." COH 29. But the record is undisputed that Genentech demanded royalties on the ground that Synagis® was an infringing product that petitioner was manufacturing and selling. J.A. 419, 428. City of Hope otherwise concedes that whether "reasonable apprehension of suit" is a part of Article III "might well raise questions that merit the Court's attention in some future case." COH 30. Genentech likewise offers little defense of "reasonable apprehension of suit." It vaguely suggests that the Federal Circuit's rule "captures the right concept," Gen. 14, discerns "[s]omething like" it in the cases, *id.* 37, but calls it "an interesting jurisprudential problem" not to be addressed here, *id.* 39.

Respondents apparently have come to recognize that "reasonable apprehension of suit"—defined by the Federal Circuit to exclude all licensees in good standing—is irreconcilable with *Maryland Casualty* and *Aetna*, as well as with this Court's explanation in *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 96 (1993), that "[m]erely the desire to avoid the threat of a 'scarecrow' patent" may satisfy the Declaratory Judgment Act. "The existence of an invalid

patent may substantially impair the economic position of those who market articles which infringe such a patent, even though no infringement suits may be immediately threatened." *Altvater*, 319 U.S. at 371 (opinion of Frankfurter, J.).

3. Justiciability.

Avoiding the decisive precedents, respondents have turned instead to what they call "basic legal principles going back 1500 years," Gen. 14, plus a list of textbook Article III objections. Respondents' project to reconstitute Article III declaratory-judgment law leads them to disdain decisions of the Second Circuit ("confusion"), the Third Circuit ("semantic imprecision"), the Seventh Circuit (same), COH 39 & n.20, and even of this Court ("*Lear* reflected *Hazeltine*'s confusion;" "extravagant patent misuse theories;" "one-sidedness was a defect in *Lear*"), *id.* 37, 41. Respondents also reject leading treatises. Gen. 35 n.25 (faulting *Moore's* for relying on the cases that rejected respondents' position). Respondents further complain of "other cases where lower courts have adjudicated declaratory claims in the absence of a ripe conventional controversy under Article III." COH 20. On the other hand, respondents repeatedly rely on decisions long overruled.[4]

A. *Standing.*

1. Respondents challenge standing. The Declaratory Judgment Act allows relief for "any interested party." 28 U.S.C. § 2201(a). Petitioner is a very "interested party." Facing multi-million-dollar royalty payments on the one hand, and risk of injunction, treble damages and other sanctions on the other, petitioner is the most interested party imaginable, not "everyman." *Bennett* v. *Spear*, 520 U.S. 154, 166 (1997).

---

[4] In addition to several pre-*Lear* cases, Genentech twice cites *Willing* v. *Chicago Auditorium Ass'n*, 277 U.S. 274 (1928), which cast doubt on whether Article III would permit federal courts to rule on declaratory judgments. Gen. 22 n.15, 38. Five years later in *Nashville, C. & St. L. Ry.* v. *Wallace*, 288 U.S. 249, 262 (1933), this Court unanimously held otherwise and left *Willing* "explained away" and "in effect . . . overruled." Borchard, *Justiciability*, 4 U. CHI. L. REV. 1, 3-4 (1936).

Petitioner "personally has suffered some actual or threatened injury" that "fairly can be traced to the challenged action" of respondents and will be "redressed by a favorable decision." *Valley Forge Christian College* v. *Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 472 (1982) (internal quotation marks omitted); *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). And the dispute arises in "a concrete factual context." *Valley Forge*, 454 U.S. at 472. This is not a case about "value interests of concerned bystanders." *Id.* at 473, quoting *United States* v. *SCRAP*, 412 U.S. 669, 687 (1973); *cf. DaimlerChrysler*, 126 S. Ct. at 1864 (rejecting taxpayer standing). This is not a complaint asserting a vague intention to visit Sri Lanka some day. *Lujan*, 504 U.S. at 563-64.

Vermont Agency v. *United States ex rel. Stevens*, 529 U.S. 765 (2000), has no kinship with this case. Petitioner is not some observer "who has placed a wager upon the outcome." Gen. 18, quoting 529 U.S. at 772. This asserted royalty obligation is not "[a]n interest unrelated to injury in fact," or a "by-product" of a legal dispute. *Id.* at 772, 773. This *is* the legal dispute. Petitioner's payments under protest in response to Genentech's demands do not mean that petitioner is not injured. They demonstrate the opposite.

2. Genentech at one point suggests that petitioner and respondents do not have adverse legal interests. Gen. 15. That sort of argument was disposed of in *Aetna*, 300 U.S at 242 ("the parties had taken adverse positions with respect to their existing obligations . . . . an adjudication of present right upon established facts"). The very decision under review here acknowledges that "[l]icensor and licensee always have adverse legal interests . . . ." P.C.A. 8a (quotation marks omitted).

3. Genentech invokes, albeit in cloudy fashion, the ancient maxim of *volenti non fit injuria*, "wrong is not committed against one who consents."[5] It contributes nothing to the

---

[5] See generally P. STEIN, REGULAE IURIS 148-49 (1966). The phrase came to be identified with the tort doctrine of assumption of risk. See

analysis, and it certainly does not overrule *Aetna, Maryland Casualty* and *Altvater*. Contracts are by their nature consensual, but that has never impeded resolution of disputes about unbreached contracts under the Declaratory Judgment Act.[6] Such disputes were a prominent reason for its enactment. See Pet. Br. 30. Indeed, declarations as to whether a contract may be terminated are one of the most common uses of the Act. 12 J. MOORE *et al.*, MOORE'S FEDERAL PRACTICE § 57.80 at 57-139 (3d ed. 2006). Petitioner never consented to pay royalties on an invalid patent, nor for non-infringing products. See pp. 10-11, *infra*. The patent on which Genentech demanded royalties did not even exist until four years after the license contract. And petitioner never promised not to sue. Moreover, *volenti non fit injuria* was a principle subject to overriding public policy;[7] the interest in patent challenges is the public's, not just a private party's. *E.g.*, *Cardinal Chemical*, 508 U.S. at 100.

4. Respondents' suggestion that jurisdiction should be declined for "prudential" reasons, Gen. 40, COH 32-34, 49-50, is far-fetched. Federal courts do not decline jurisdiction lightly, *Marshall* v. *Marshall*, 126 S. Ct. 1735, 1741 (2006), and patent validity and infringement are issues unquestionably assigned by statute to their jurisdiction. 28 U.S.C. § 1338(a). The patent laws regulate the interest in using ideas in the

---

Warren, *Volenti Non Fit Injuria in Actions of Negligence*, 8 HARV. L. REV. 457, 459 (1895).

[6] Perhaps for that reason, Genentech asserts—in spite of the explicit contract count in the complaint, J.A. 136—that petitioner "is not seeking a declaration of rights under the terms of the parties' contract," Gen. 10. But the complaint expressly prayed for a declaration of rights under the license agreement. J.A. 147. Genentech acknowledged in the District Court that petitioner "seeks a declaration that it owes nothing under its license agreement with Genentech because its sales of Synagis® allegedly do not infringe any valid claim of the '415 patent." C.A.A. 2827.

[7] See RESTATEMENT (2D), TORTS § 496C(2)(1965); Friedmann, *Social Insurance and the Principles of Tort Liability*, 63 HARV. L. REV. 241, 251 (1949).

pubic domain that petitioner seeks to exercise. "Prudential standing," as explained in a case both respondents cite, encompasses "[1] the general prohibition on a litigant's raising another person's legal rights, [2] the rule barring adjudication of generalized grievances more appropriately addressed in the representative branches, and [3] the requirement that a plaintiff's complaint fall within the zone of interests protected by the law invoked." *Elk Grove Unified School Dist.* v. *Newdow*, 542 U.S. 1, 12 (2004), quoting *Allen* v. *Wright*, 468 U.S. 737, 751 (1984). None of those remotely fits here.

B. *Ripeness.*

Respondents also challenge ripeness. Gen. 17, 21, 24-25, 31; COH 29-30. But the "primary purpose" of the Declaratory Judgment Act "was to enable persons to obtain a definition of their rights before an actual injury had occurred." *Steffel* v. *Thompson*, 415 U.S. 452, 478 (1974) (Rehnquist, J., concurring). It provides "an alternative to pursuit of . . . arguably illegal activity." *Id.* at 480. Ripeness here is apparent from three independent lines of well-established authority: (1) cases interpreting contracts before breach; (2) pre-enforcement interpretations of statutes and regulations; and (3) cases testing the validity of patents prior to any infringement.

1. The courts of appeals for decades under Article III and the Declaratory Judgment Act have adjudicated contract disputes—including patent-license disputes—without requiring breach, just as is contemplated in Fed. R. Civ. P. 57. See Pet. Br. 18-20, 33-34; Pet. Cert. 13-16. The disruption that would ensue if the Federal Circuit's view of Article III prevailed would affect commercial disputes of all kinds—especially insurance and contract disputes, which were a particular concern of the Declaratory Judgment Act. See Pet. Cert. 14-16, 21; Pet. Br. 13, 29.

2. Respondents acknowledge that a threat to enforce a law against one challenging it is "a *present* invasion" and "creates a ripe controversy regardless of whether the plaintiff complies with the law or defies it." COH 18 (emphasis in original).

The Act applies when "compliance is coerced by the threat of enforcement, and the controversy is both immediate and real." *Lake Carriers' Ass'n* v. *MacMullan*, 406 U.S. 498, 508 (1972). Here failure to pay royalties would risk not only contract damages but also liability for patent infringement, 35 U.S.C. § 271, which can carry statutory sanctions punitive in nature, 35 U.S.C. § 284. See *Avia Group Int'l, Inc.* v. *L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1566 (Fed. Cir. 1988) (patent treble damages "deter willful patent infringement by punishing"); *Altvater*, 319 U.S. at 365 ("the involuntary or coercive nature of the exaction preserves the right . . . to challenge the legality of the claim").

3. From the first year of the Declaratory Judgment Act it was recognized that declaratory actions to test patent validity could be brought by parties who have produced an allegedly infringing product "or have actually prepared to produce such a device." *Jervis B. Webb Co.* v. *Southern Sys., Inc.*, 742 F.2d 1388, 1399 (Fed. Cir. 1984); see *Zenie Bros.* v. *Miskend*, 10 F. Supp. 779 (S.D.N.Y. 1935). Petitioner, of course, already manufactures and sells Synagis®, the allegedly infringing product.

4. Ripeness decisions usually address the timing of challenges to administrative rules or rulings, and in that context consider "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs.* v. *Gardner*, 387 U.S. 136, 149 (1967); see *National Park Hospitality Ass'n* v. *Department of Interior*, 538 U.S. 803, 808 (2003); *Public Serv. Comm'n* v. *Wycoff Co.*, 344 U.S. 237, 243 (1952) (prematurity a concern "especial[ly] in the field of public law"). Patent validity and infringement certainly are fit issues for judicial resolution; courts determine them all the time. The hardship on all parties, even on respondents, of not adjudicating the issue also is clear: either respondents stop receiving substantial royalty payments while petitioner risks the consequences of patent infringement, or petitioner continues to pay royalties on a patent which may be invalid, and if so by its existence harms

not just petitioner but the public as well. A breach of the license agreement would not make the record more precise.

Moreover, "the appropriate standard for determining ripeness of private party contract disputes is the traditional ripeness standard, namely, whether 'there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *Principal Life Ins. Co.* v. *Robinson*, 394 F.3d 665, 671 (9th Cir. 2005), quoting *Maryland Casualty*, 312 U.S. at 273. This dispute is not about what respondents choose to call "facts that are hypothetical." COH 20. Adjudication does not require "powers of imagination." *Texas* v. *United States*, 523 U.S. 296, 301 (1998).[8]

5. Respondents argue that this record does not establish a sufficient controversy. But the allegations of the complaint are backed up with uncontroverted and documented declarations of conversations and correspondence reflecting a demand for royalties by Genentech and protest and apprehension of suit by petitioner. See J.A. 388 ("clear threat" of suit), 393, 419, 421, 426, 428, 431. Respondents have never denied that if petitioner stopped paying royalties, suit for patent infringement or breach of contract, or both, would follow.

4. The License.

1. Respondents scarcely mention the actual provisions of the license. This license contains no promise by petitioner not to sue. Genentech disclaims any warranty that the patent is valid. J.A. 411. And the license applies only to products that infringe a valid patent. J.A. 399, C.A.A. 3586.

Genentech complains that "MedImmune did not . . . negotiate any term that would permit it to initiate a judicial pro-

---

[8] Analogy to the old equity bill of *quia timet*, see Gen. 22, does not advance this case. Indeed, *quia timet* would comfortably fit these circumstances: it protected parties from "future injury," *Borey* v. *National Union Fire Ins. Co.*, 934 F.2d 30, 32 (2d Cir. 1991), and was "generally used to prevent wrongs before they occurred." Raack, *A History of Injunctions in England Before 1700*, 61 IND. L.J. 539, 550 n.59 (1986).

ceeding challenging the validity of the patents while retaining the benefits of the license." Gen. 7. But nothing in the law says that subject-matter jurisdiction demands that a patent licensee must have obtained the licensor's permission to sue. And, by the same token, Genentech did not negotiate any term that would bar petitioner from suing, without termination, to invalidate the patent—even though the record shows that in other licenses Genentech has done precisely that, obtaining (in spite of *Pope Mfg. Co.* v. *Gormully*, 144 U.S. 224, 235 (1892), and *Lear*) the licensee's promise not to challenge validity. C.A.A. 1702, referenced J.A. 274. Genentech's reasoning would imply a ban on challenging patent validity into every license contract, and even a ban on federal subject-matter jurisdiction as well.

2. Respondents argue that a license should be treated as if it were a settlement of a lawsuit. But it is not, and even if it were, a settlement agreement would be a defense on the merits, not a bar to federal subject-matter jurisdiction. "[A]bsence of a valid . . . cause of action does not implicate subject-matter jurisdiction." *Steel Co.* v. *Citizens for a Better Environment*, 523 U.S. 83, 89 (1998). Also, if a settlement agreement contained a provision prohibiting a patent challenge, it would be unenforceable as contrary to *Lear*. Pet. Br. 37; *Business Forms Finishing Serv., Inc.* v. *Carson*, 452 F.2d 70, 73-75 (7th Cir. 1971) (Stevens, J.); *Kraly* v. *National Distillers & Chem. Corp.*, 502 F.2d 1366, 1369 (7th Cir. 1974); *but see Flex-Foot, Inc.* v. *CRP, Inc.*, 238 F.3d 1362, 1368 (Fed. Cir. 2001).

3. Moreover, to transmute a license into a litigation settlement is an unsupportable stretch. The law for centuries has defined a license, not as a settlement of a dispute, but as "[a] permission, usu[ally] revocable, to commit some act that would otherwise be unlawful." BLACK'S LAW DICTIONARY 938 (8th ed. 2004). A lease on an apartment or house is not a settlement of a trespass claim by the landlord. A lease dispute meets the standards of Article III and the Declaratory Judgment Act even when the tenant has not committed a

breach. *118 East 60th Owners, Inc.* v. *Bonner Properties, Inc.*, 677 F.2d 200, 202 n.1 (2d Cir. 1982); Pet. Br. 19-20. The license in this case specifically did not resolve the validity of any patent. J.A. 411. The patent, indeed, was not issued (and then under very unusual circumstances) until four years after the license. See J.A. 509; Pet. Br. 4-6.

4. Even if licenses were private settlements, the interests in an action challenging patent validity are not purely private. Also at stake is restoration of public ideas to the public domain. For that reason there is a strong federal policy favoring patent challenges. See Pet. Br. 13, 35; *Cardinal Chemical*, 508 U.S. at 100 (validity of patent should be determined even after determination that product did not infringe).[9]

5. "Settled Expectations."

Respondents say that to reverse the Federal Circuit would upset "settled expectations." COH 12. That is demonstrably not so.

1. For nearly a year after this case was filed, neither respondent moved to dismiss for lack of subject-matter jurisdiction. They did not do so until the Federal Circuit issued *Gen-Probe*; then they did so at once. There was indeed, as the district court in *Gen-Probe* called it, "settled law," see Pet. Br. 40 & n.16—and it was settled the opposite way, including in one of the Federal Circuit's first and leading decisions, *C.R. Bard, Inc.* v. *Schwartz*, 716 F.2d 874 (Fed. Cir. 1983)—whose authority the District Court, like the district court in *Gen-Probe*, pointed out, P.C.A. 30a, but which respondents' briefs scarcely acknowledge.[10]

2. The fact is, *Gen-Probe* was a shock that took both the bench and the bar by surprise. In *Gen-Probe* itself, the issue did not come up until two years into the case, when after

---

[9] One respondent maintains that "the only substantive rights created by Congress belong to Respondents;" it contends also that "any potential justiciable controversy is either moot or unripe." COH 25, 28.

[10] Genentech mentions *C.R. Bard* once in a footnote, Gen. 34 n.25; City of Hope does not acknowledge it at all.

losing at trial, the *Gen-Probe* patentee moved to dismiss for lack of subject-matter jurisdiction. The district court there emphatically denied the motion, as contrary to "settled law," see Pet. Br. 40, but the Federal Circuit announced the new *Gen-Probe* constitutional doctrine. In *Centocor* yet another district court denied such a jurisdictional objection—then reversed itself after *Gen-Probe*. See Pet. Br. 40.

3. Treatise-writers and scholars shared the same understanding. *E.g.*, B. BRUNSVOLD & D. O'REILLEY, DRAFTING PATENT LICENSE AGREEMENTS 167 (5th ed. 2004) (licensee has "freedom to contest the validity of the licensed patent at any time"); McCarthy, *"Unmuzzling" the Patent Licensee*, 59 J. PAT. OFF. SOC'Y 544, 554 (1977) ("consistent with the purposes of declaratory judgments" and more desirable than breach); Fisher, *The Licensee's Choice*, 6 TEXAS INTELL. PROP. L.J. 1, 12 (1997) (citing *C.R. Bard*); 12 J. MOORE *et al.*, § 57.22[8][c][i] at 57-80 ("licensee need not terminate the license in order to maintain a federal declaratory relief action for patent invalidity," citing *inter alia C.R. Bard*).[11]

6. *Lear* and Licensee Estoppel.

1. It is remarkable that Genentech opens its brief by citing *Kinsman* v. *Parkhurst*, 18 How. 289 (1856), the very case identified by this Court as having established the doctrine of licensee estoppel, *Lear*, 395 U.S. at 663—which *Lear* explicitly overruled. *Id.* at 671. And the same brief closes by urging a return to "[t]he traditional understanding that a license resolves any cognizable dispute over the validity of the patent" if the license is in place. Gen. 50.

---

[11] Respondents argue that *Gen-Probe* somehow was foreshadowed in *Studiengesellschaft Kohle m.b.H.* v. *Shell Oil Co.*, 112 F.3d 1561 (Fed. Cir.), *cert. denied*, 522 U.S. 996 (1997), a case that did not concern federal subject-matter jurisdiction (but did have dicta severely critical of *Lear*). 112 F.3d at 1567. Neither respondent cited the case in the Court of Appeals, and it was barely mentioned in *Gen-Probe*. See Gen. 35 n.25, COH 6, 49; 359 F.3d at 1381.

That might have been the "traditional understanding" *prior to Lear*. Respondents repeatedly seek authority in Nineteenth-Century decisions of this Court that, indeed, may have reflected the law once upon a time, but were explicitly rejected in *Lear*. *E.g.*, Gen. 7, COH 35, 49, relying on *United States* v. *Harvey Steel Co.*, 196 U.S. 310 (1905), a case particularly criticized in *Lear*, 395 U.S. at 664. City of Hope invokes "the centuries-old equitable rule of licensee estoppel," COH 11, and praises the Federal Circuit's "reaffirmation of the historical scope of licensee estoppel," *id.* 50. Some of respondents' *amici* urge that "the Court should overrule or clarify *Lear v. Adkins*." Donaldson Br. 1.[12]

2. Licensee estoppel, even if it were still a permitted defense, is not and never was a *jurisdictional* defense.

3. Both respondents complain that declaratory relief would allow petitioner to "have its cake and eat it too." Gen. 43; COH 47-48. The same was argued unsuccessfully in *Lear*. The same might just as easily be said of the innumerable contract declaratory-judgment cases brought without breach; see, *e.g.*, Fed. R. Civ. P. 57 advisory comm. note; Pet. Br. 33. Moreover, the situation is not at all one-sided. Genentech is continuing to obtain the royalties called for in the license. Petitioner is providing the very income stream that patent owners say is so important to them. See Columbia Br. 4.

This Court in *Lear* considered and rejected such pleas of unfairness. "[T]he equities of the licensor do not weigh very heavily when they are balanced against the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." *Lear*, 395

---

[12] One respondent even accuses the *Lear* opinion of "confusion" and of having "misread several cases it relied on," as well as of "one-sidedness." COH 37, 38 n.19, 41. It is unusual for *Lear*'s author to be faulted on judicial craftsmanship or evenhandedness. *Cf.* Friendly, *Mr. Justice Harlan, as Seen by a Friend and Judge of an Inferior Court*, 85 HARV. L. REV. 382, 384 (1971) ("there has never been a Justice of the Supreme Court who has so consistently maintained a high quality of performance").

U.S. at 670. "[I]t does not seem to us to be unfair to require a patentee to defend the Patent Office's judgment when his licensee places the question in issue . . . ." *Id.* See also *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470, 488-89 (1974).

7. Discretion.

Respondents now argue, for the first time in this litigation, that if subject-matter jurisdiction exists, this Court nevertheless should hold that declaratory relief must be denied as a matter of discretion. Gen. 41, COH 32.

1. Respondents concede, Gen. 40, COH 49, that this new prayer was not decided or even raised in either the District Court or the Federal Circuit, and was not mentioned in respondents' brief in opposition to certiorari. Hence no record to support (or oppose) such a ruling was made. "While it is true that a respondent may defend a judgment on alternative grounds, we generally do not address arguments that were not the basis for the decision below." *Matsushita Elec. Indus. Co.* v. *Epstein*, 516 U.S. 367, 379 n.5 (1996); see also *Ponte* v. *Real*, 471 U.S. 491, 500 (1985). "Prudence . . . dictates awaiting . . . developed arguments on both sides and lower court opinions squarely addressing the question." *Yee* v. *City of Escondido*, 503 U.S. 519, 538 (1992).

2. The District Court was precluded from exercising discretion by the Federal Circuit's announcement in *Gen-Probe* that district courts absolutely lack Article III jurisdiction in such cases, a ruling which the District Court despite "serious misgivings" obeyed. P.C.A. 30a-31a. The appellate exercise of discretion that respondents now ask for would be contrary to longstanding practice in declaratory-judgment cases. Such exercise of discretion is committed in the first instance to the district court. *E.g.*, *Brillhart* v. *Excess Ins. Co.*, 316 U.S. 491, 498 (1942). Discretion, of course, "is not whim," *Martin* v. *Franklin Capital Corp.*, 126 S.Ct. 704, 710 (2005), but it is not applied initially by appellate courts:

> "We believe it more consistent with the [declaratory judgment] statute to vest district courts with discretion in

> the first instance, because facts bearing on the usefulness of the declaratory judgment remedy, and the fitness of the case for resolution, are peculiarly within their grasp."

Wilton v. *Seven Falls Co.*, 515 U.S. 277, 289 (1995), discussed at Pet. Br. 44. *Cf.* also *Cardinal Chemical*, 508 U.S. at 102-103 (remanding for discretion to be exercised); *id.* at 103 (Scalia, J., concurring in part and in judgment) ("failure to exercise *any discretion at all*") (emphasis in original).[13]

3. Respondents seek a categorical rule that even if there is Article III subject-matter jurisdiction, declaratory judgments of patent validity must always be held an abuse of discretion when the licensee is not in breach. Gen. 41, COH 32-33. But "[t]he lower federal courts ought not to be narrowly confined in determining whether a declaratory judgment is an appropriate remedy under all the circumstances." *Altvater*, 319 U.S. at 370 (opinion of Frankfurter, J.). Just last Term in *eBay, Inc.* v. *MercExchange, L.L.C.*, 126 S. Ct. 1837, 1841 (2006), a case addressing equitable relief,[14] this Court underscored the very point:

> "Just as the District Court erred in its categorical denial of injunctive relief, the Court of Appeals erred in its categorical grant of such relief."

This Court unanimously vacated and remanded "so that the District Court may apply that [traditional equity four-factor] framework in the first instance." *Id.* Four Justices further emphasized that "courts should apply the well-established,

---

[13] See also *Maryland Cas. Co.* v. *United Corp.*, 111 F.2d 443, 446 (1st Cir. 1940) (Magruder, J.) ("Since the complaint was dismissed on the mistaken ground of lack of jurisdiction, the judgment appealed from should not be affirmed, even if there existed adequate grounds on which the complaint might have been dismissed as a matter of discretion.").

[14] Respondents often elide the distinction between equitable discretion and discretion under the Declaratory Judgment Act. There can be "critical distinctions which make declaratory relief appropriate where injunctive relief would not be." *Steffel*, 415 U.S. at 581 (Rehnquist, J., concurring). See also, *e.g.*, *Maryland Casualty*, 312 U.S. at 274 (denying injunction but granting declaratory judgment).

four-factor test—without resort to categorical rules." *Id.* at 1842 (Kennedy, J., concurring).

4. Apparently under cloak of their equity analogies,[15] respondents' briefs are laced with denunciations of petitioner for having filed this lawsuit. Probably licensees who challenge patents are not likely to be popular with patent owners. One respondent recites "duplicitous," "duplicity," "duplicitously." Gen. 8, 42, 43; see also Qualcomm Br. 8, 9, 10 ("treachery" "duplicity," "perfidy"); Colum. Br. 2, 5 ("pernicious").[16]

Respondents describe this litigation as "license and then sue." Gen. 42; COH 8 n.4. But overlap of biotechnology patents makes widespread licensing a necessity for new products. In fact, petitioner, to remove any doubt that it could legally develop and market Synagis®, took licenses under nearly two dozen other patents besides the one at issue; the validity of only one of those is under challenge. See *MedImmune, Inc.* v. *Centocor, Inc.*, No. 05-656. The license here was agreed to in 1997; the patent at issue did not come into existence until late 2001; this action was filed in 2003.

Petitioner has continued to pay royalties and do business with Genentech, including negotiating later license agreements under the patent for other products. Respondents now call that "inequitable." Gen. 43; see COH 7. But those later licenses are not at issue here, nor are they relevant to federal subject-matter jurisdiction. And both parties well knew that their dispute as to Synagis® remained unresolved; they discussed both the present dispute and the later licenses in the same letters. See, *e.g.*, J.A. 426, 429, 431, 433-35. Respondents ignore that

---

[15] If equities were to be balanced, Genentech's facially extraordinary conduct in obtaining the patent would certainly need to be explored and considered. See Pet. Br. 4-6.

[16] Severe denunciation apparently is frequent in contemporary biotechnology litigation. City of Hope in a pending case accuses Genentech of "cheating and deception." City of Hope's Answer Brief, *City of Hope Nat'l Med. Ctr.* v. *Genentech, Inc.*, No. S129463, S. Ct. Cal. (Sept. 19, 2005) at 63; see also *id.* at 102 ("Genentech stonewalled, lied, and cheated"); 103 ("trickery" "deceit").

a prominent stated purpose of the Declaratory Judgment Act was to encourage parties to continue their ongoing commercial relationships, allowing particular disputes to be resolved judicially *without* breaches of contract. See Pet. Br. 29-31.

Petitioner submits that it has respected the letter and purpose of the patent laws. Petitioner did not resort to a breach of contract, which not only would have put petitioner in jeopardy, but also would have deprived Genentech of substantial royalties and, if the patent were upheld, could have led to an injunction that would take a unique life-saving medicine for infants off the market.

8. Practical Consequences.

1. Any public or commercial benefit from reinterpreting the Constitution, forcing licensees to escalate validity disputes into high-stakes patent-infringement litigation, is difficult to discern. Respondents show none—unless it were considered beneficial to make patent validity challenges less frequent and far more dangerous. Up to now, however, federal patent policy, recognized by this Court, has been to "*encourage* authoritative testing of patent validity." *Blonder-Tongue Labs.* v. *University of Ill. Found.*, 402 U.S. 313, 344 (1971) (emphasis supplied). Congress has shown no inclination to change that. That has also been the view endorsed by the Executive Branch for decades,[17] as it is once again here. See Brief for the United States as *Amicus Curiae* Supporting Petitioner (reflecting views of Patent and Trademark Office, the National Institutes of Health, and other federal agencies) 1-2, 27; FTC, TO PROMOTE INNOVATION (2003) (cited in *eBay*, 126 S. Ct. at 1842 (Kennedy, J., concurring)); Pet. Br. 36, 45-48.

2. Some *amici* prophesy, if the Federal Circuit's new doctrine is reversed, "thousands, even millions, of licensees" filing suits against patent holders. Qualcomm Br. 11. One

---

[17] *E.g.*, Brief for the United States as *Amicus Curiae*, *Lear, Inc.* v. *Adkins*, No. 56, OT 1968 (Oct. 25, 1968) at 23 ("The patentee is not a victim of unfair dealing merely because his licensee challenges the patent.").

even surprisingly predicts that licensees will do so "no matter whether the case for invalidity is strong or weak." Boston PLA Br. 19. No evidence supports such speculation. As others recognize, "patent litigation is notoriously expensive," Allison Br. 8, "enormously expensive," 3M Br. 12; see *Blonder-Tongue*, 402 U.S. at 334; Pet. Br. 45. No one has claimed that any flood of lawsuits occurred after *Lear*.

3. Just as unsupported are lamentations that if licensees once again may sue without breach, patentees might stop issuing licenses. But licenses are how patentees make money. "[A] large part of [a patent's] value consists in the profits derived from royalties and license fees." *Waterman* v. *Mackenzie*, 138 U.S. 252, 260 (1891). "[L]icensing fees are among the most important rewards that a patent owner garners from a valid patent." Qualcomm Br. 24. Licensing did not stop after *Lear*, and licenses have been granted by the thousands under the pre-*Gen-Probe* law.

Likewise, to predict that licenses might cost more, Gen. 47, COH 44, is entire speculation. Royalty rates are a product of bargaining power and market forces.[18] At least as likely, concern about validity challenges would cause patentees to charge less, especially for weak patents, calculating that licensees who pay less are less motivated to mount expensive challenges. And, of course, to the extent invalid patents would no longer distort the market, prices to consumers would tend to fall, and innovation rise.

4. Finally, the desirability or utility of demanding contract breaches and unauthorized infringement before resolving dis-

---

[18] Respondents insist, without evidence and without explanation of relevance, that this license came at bargain rates. Gen. 6, 28, 43, 48-49; COH 5, 34. But rates presumably reflect market forces. "A patent empowers the owner to exact royalties as high as he can negotiate . . . ." *Brulotte* v. *Thys Co.*, 379 U.S. 29, 33 (1964). There is no evidence that Genentech behaved any differently.

putes is not self-evident.[19] It certainly was not what was intended by those who advocated and adopted the Declaratory Judgment Act. See Pet. Br. 29-31. And Congress does not treat infringement as blameless. Patent infringement often carries punitive sanctions of treble damages. *E.g.*, 35 U.S.C. § 284 (treble damages for willful patent infringement); see also 17 U.S.C. § 506 (criminal penalties for willful copyright infringement).

Any rule that would substantially discourage patent challenges by the parties most knowledgeable and motivated to bring them, see *Lear*, 395 U.S. at 670, by escalating the cost and risk of doing so, is contrary to the purpose of the patent laws as emphatically and repeatedly held by this Court. *E.g.*, *Lear; Blonder-Tongue; Cardinal Chemical.* "[S]ometimes *too much* patent protection can impede rather than 'promote the Progress of Science and useful Arts'. . . ." *Laboratory Corp.* v. *Metabolite Labs., Inc.*, 126 S. Ct. 2921, 2922 (2006) (Breyer, J., dissenting from dismissal) (emphasis in original). Just as "[t]he Fourteenth Amendment does not enact Mr. Herbert Spencer's Social Statics," *Lochner* v. *New York*, 198 U.S. 45, 75 (1905) (Holmes, J., dissenting), so Article III did not build into the Constitution the barrier to patent challenges that respondents advocate.

CONCLUSION

For the reasons stated herein and previously, the judgment should be reversed.

---

[19] "The inviolability of contracts, and the duty of performing them, as made, are foundations of all well-ordered society . . . ." *Murray* v. *Charleston*, 96 U.S. 432, 449 (1877). *Compare* Holmes, *The Path of the Law*, 10 HARV. L. REV. 457, 462 (1897) (breach of contract not a moral issue), *with* C. FRIED, CONTRACT AS PROMISE: A THEORY OF CONTRACTUAL OBLIGATION 16 (1981) ("[a]n individual is morally bound to keep his promises . . . ."); see Sharp, *Pacta Sunt Servanda*, 41 COLUM. L. REV. 783 (1941).

Respectfully submitted,

HARVEY KURZWEIL
ALDO A. BADINI
HENRY J. RICARDO

DEWEY BALLANTINE LLP
1301 Avenue of the Americas
New York, New York 10019
(212) 259-8000

WILLIAM C. BERTRAND, JR.
JONATHAN KLEIN-EVANS

MEDIMMUNE, INC.
1 MedImmune Way
Gaithersburg, Maryland 20878
(301) 398-4625

JOHN G. KESTER *
PAUL B. GAFFNEY
JANET C. FISHER
AARON P. MAURER
MICHAEL T. MORLEY

WILLIAMS & CONNOLLY LLP
725 12th Street, N.W.
Washington, D.C. 20005
(202) 434-5000

ELLIOT M. OLSTEIN

CARELLA BYRNE BAIN
GILFILLAN CECCHI
STEWART & OLSTEIN
Five Becker Farm Road
Roseland, New Jersey 07068
(973) 994-1700

Attorneys for Petitioner

August 30, 2006

* Counsel of Record